Department of Health and Human Services Public Health Service

Food and Drug Administration
Rockville, MD 20857

JUL 23 2007

Re: da VINCI System
Docket No. 2001E-0095

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop: Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This letter responds to your April 9, 2002, request for comments regarding the application for patent term extension for U.S. Patent No. 5,808,665 filed by SRI International (SRI) under 35 U.S.C. § 156. The medical device claimed by the patent is the da VINCI System (endoscopic instrument control system and endoscopic instruments).

In your letter of November 27, 2000, you requested confirmation that (1) the da VINCI System, was subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use, and (2) the application for patent term extension was filed within 60 days after the device was approved. You raised the issue of the regulatory review period because you say the *approval* for commercial marketing was under § 510(k) of the Federal Food, Drug, and Cosmetic Act (FFDCA).[1] We responded to your request on October 2, 2001, stating that according to the Food and Drug Administration's (FDA's) records, the product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(g). We also stated that the 510(k) application was *approved* on July 11, 2000, which made the submission of the patent term extension application on September 11, 2000, not timely within the meaning of 35 U.S.C. § 156(d)(1).

In your November 14, 2001, Notice of Final Determination of Ineligibility, you determined that the U.S. Patent No. 5,808,665 claiming the medical device the da VINCI System is ineligible for patent term extension under 35 U.S.C. § 156. You stated that the da VINCI System underwent regulatory review under § 510(k) of the FFDCA. For regulatory review of a medical device claimed by a patent to give rise to eligibility for patent term extension, the regulatory review must have been conducted under § 515 of the FFDCA (21 U.S.C. 360e). Because the regulatory review of the da VINCI system was under § 510(k) of the FFDCA, you stated the patent is not eligible for patent term extension. You also noted that 60 days after the *approval* date of the device was Saturday, September 9, 2000, and that the application for patent term

[1] 21 U.S.C. 360(k).

extension was filed on Monday, September 11, 2000, the next succeeding business day following the within 60 days of product approval filing requirement. You stated the application was timely filed.

In its January 9, 2002, request for reconsideration, SRI notes that FDA determined in the October 2, 2001, letter that the da VINCI System was subject to a regulatory review period. SRI believes they are entitled to a patent term extension because the regulatory review of the da VINCI System was conducted under both § 515 and § 510(k) of the FFDCA, with *approval* being granted under § 510(k).

We have reexamined our records and consulted with the Center for Devices and Radiological Health (CDRH) and have concluded that our October 2, 2001, eligibility determination was in error. In fact, a review of FDA's official records indicates that this product was not subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4).

The da VINCI System was initially submitted on January 19, 1999, under § 510(k) of the FFDCA (21 U.S.C. § 360(k)). During the course of the review, there were numerous discussions among FDA management and with the sponsor regarding the appropriate regulatory path (§ 510(k) or § 515 of the FFDCA) to market the device. The CDRH Division of General and Restorative Devices referred the da VINCI System to an FDA Device Advisory Panel for review. The panel recommended to FDA that a premarket approval application (PMA) under § 515 of the FFDCA be approved with conditions. On November 29, 1999, the firm submitted a PMA for review of the device. During the course of the review, it was determined that the device represented an expanded use of a previously cleared 510(k) device and the da VINCI System did not raise new issues of safety and effectiveness when compared to previously cleared models and cleared uses. Consequently, it was decided that the appropriate path to market for this device should be through a 510(k) application rather than a PMA. On June 20, 2000, the PMA was closed and the 510(k) application was reopened. On July 11, 2000, the device was determined to be substantially equivalent (for the indications for use stated in the labeling) to legally marketed predicate devices and cleared for marketing under § 510(k) of the FFDCA.[2]

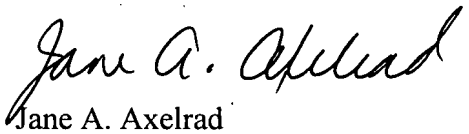
Although the da VINCI System was reviewed for a time under § 515 of the FFDCA, it was not approved under § 515. Because this device was not approved under § 515 of the FFDCA, it was not subject to a regulatory review period as defined under 35 U.S.C. §156(g)(3)(B)(ii), and it is ineligible for patent term extension. In its request for reconsideration, SRI contends that its device is eligible for patent term extension because regulatory review "was conducted under both sections 515 and 510(k) of Chapter 5 of the FFDCA." However, the definition of a *regulatory review period* states that it includes "the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date *such*

[2] An FDA finding of substantial equivalence of the device to a legally marketed predicate device results in a classification for the device and clears it for commercial distribution. It does not mean that FDA approves the device.

application was *approved* under such Act . . . ." (35 U.S.C. § 156(g)(3)(B)(ii)) (emphasis added). The term *such application* in this provision refers to the application under § 515 of the FFDCA. Premarket submissions under § 510(k) of the FFDCA are not *approved* by FDA (See 21 CFR 807.97). The definition of *regulatory review period* thus requires that an application for the device be submitted under § 515 and also that the application under § 515 be approved. Since an application under § 515 was not approved for the da VINCI system, it is ineligible for patent term extension.

Please let me know if we can be of further assistance.

Sincerely,



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